

The Regulation and
Quality Improvement
Authority

Our ref: GH/kmcc

Your Ref: JOH-0440-14

14 April 2014

Mr John O'Hara QC
The Inquiry into Hyponatraemia-related Deaths
Arthur House
Arthur Street
BELFAST
BT1 4GB

Dear Mr O'Hara

Thank you for your letter of 27 March 2014.

RQIA is the independent body that regulates and inspects the quality and availability of health and social care services in Northern Ireland. RQIA was established in 2005 by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

The general duties of RQIA are set out in Part II, Article 4 (2) of the Order. Other duties are describes in Articles 5, 6 and 7.

The general duty of quality for the Health and Social Services Board, and each HSS Trust is described in Articles 34 (1) and (2).

Article 35 (1) describes the roles of RQIA in respect of investigations, reviews and inspections of health and personal social services, for which statutory bodies have responsibility.

I will respond to the specific points in your letter in the order in which they have been raised –

1. The responsibilities and membership of both the Public Health Agency (PHA), and the Health and Social Care Board (HSCB), will be addressed by the other respondents.
2. The questions in relation to directorship appointments and the role of the HSCB will be addressed by other respondents.
3. The questions in relation to the HSC Board's role in respect of clinical governance will be addressed by other respondents.

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Established under The Health and Personal Social Services (Quality, Improvement and Regulation) (NI) Order 2003

4. Serious Adverse Incidents

The arrangements for the reporting of Serious Adverse Incidents is set out in the HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents (October 2013).

This Procedure describes the role of RQIA at section 3.6 (Page 11).

'RQIA have a statutory obligation to investigate some incidents that are also reported under the SAI procedure. In order to avoid duplication of Incident notification and investigation, RQIA will work in conjunction with the HSCB/PHA with regard to the review of certain categories of SAI. In this regard the following SAIs should be notified to RQIA at the same time of notification to the HSCB:

All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.

It is acknowledged these incidents should already have been reported to RQIA as a 'notifiable event' by the statutory or independent organisation where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being investigated as a SAI by the HSC organisation who commissioned the service.

The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in conjunction with RQIA professionals.'

The administrative protocol, at Appendix 14 (page 57), describes the steps which are taken by the HSC Board, PHA and RQIA in the circumstances where a SAI has been copied to RQIA.

RQIA does not directly receive SAI reports of adverse events which occur in acute hospitals. However, since January 2014 two RQIA directors, Mrs Kathy Fodey, Director of Regulation and Nursing and Mrs Theresa Nixon, Director of Mental Health Learning Disability and Social Work, are members of the Regional Adverse Incident Steering Group, chaired by the HSC Board.

The Steering Group reviews a selection of investigation reports, to ensure that themes, trends, best practice and learning from SAIs is identified, disseminated and implemented in a timely manner. Decisions may be notified to HSC organisations through alert letters, learning letters, newsletter, issued by the HSC Board, and through thematic review events organised by the HSC Board.

The Scrutiny Group also monitors the dissemination of alerts which need to be brought to the attention of HSC trusts. The Steering Group meets monthly and is chaired by the HSC Board Governance Manager. If there are matters which require further scrutiny or follow up, the HSC Board is required to take the necessary action.

I can advise that in addition to the steps outlined above, two senior members of RQIA staff have been seconded by DHSSPS to facilitate its review of incident reporting arrangements.

5. Engagement with Families

The arrangements for the engagement of families are described in the 'Procedure for the Reporting and Follow up of Serious Adverse Incidents', (section 5.4, page 16).

Dr Andrew McCormick, Permanent Secretary, DHSSPS, wrote to the Chief Executives of both the HSC Board and the PHA, on 31st March 2014, to advise that litigation or legal proceedings should not be an obstacle to engaging with patients, clients and families. This letter states that engagement should cover –

- *Advising patients, clients and families that the incident is being treated / investigated as an SAI*
- *Offering them the opportunity to participate, as appropriate, in the investigation process*
- *Sharing with them the findings in the form of an investigation report*
- *Providing them with information on the action being taken to apply any learning from the investigation.*

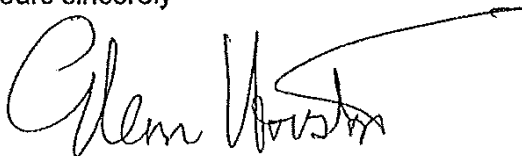
On the same date Mrs Fionnuala McAndrew, Interim Chief Executive, HSC Board, wrote to Chief Executives of all HSC Trusts advising as follows –

'the procedure for the Reporting and Follow up of SAIs (revised October 2013) makes clear the need for and importance of appropriate communication and involvement of service users, relatives and carers. However, to further assist Trusts, the HSCB and PHA have reviewed the SAI Notification Form and developed a SAI Investigation Report Checklist which should accompany all SAI Investigation Reports regardless of the investigation level'.

Mrs McAndrew, Interim Chief Executive, HSC Board and Mr Eddie Rooney, Chief Executive PHA, have also written jointly to a number of organisations, including RQIA, advising of the establishment of a joint HSC Board/PHA working group to provide greater detail on the requirements for effective family engagement in the SAI Review process. RQIA has been invited to nominate an officer to participate in this working group. The intention is to prepare draft guidance on effective family engagement which will be shared with DHSSPS before the end of May.

I trust this information is helpful.

Yours sincerely



Glenn Houston
Chief Executive.